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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,276	11/02/2001	Spencer W. Beaufore	OPME / 05	8989
26875	7590	11/24/2004	EXAMINER	
WOOD, HERRON & EVANS, LLP			BOGART, MICHAEL G	
2700 CAREW TOWER			ART UNIT	PAPER NUMBER
441 VINE STREET			3761	
CINCINNATI, OH 45202				

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/000,276	BEAUFORÉ ET AL.
	Examiner	Art Unit
	Michael G. Bogart	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 November 2001.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-55 is/are pending in the application.
 4a) Of the above claim(s) 14,16,27,29,39,41,45 and 47 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,2,4,5,12,13,17-20,26,30-32,38,42-44,48-51 and 55 is/are rejected.
 7) Claim(s) 3,6-11,15,21-25,28,33-37,40,46 and 52-54 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 02 November 2001 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/02, 5/03, 9/03</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

This application contains claims directed to the following patentably distinct species of the claimed invention:

A crush limiting member comprising one of the following:

- I. A tube member.
- II. A blade member.
- III. A stop member.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 13, 26, 38 and 44 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

During a telephone conversation with David Brinkman on 18 November 2004 a provisional election was made with traverse to prosecute the invention of II, a blade member, claims 15, 28, 40 and 46. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14, 16, 27, 29, 39, 41, 45 and 47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

Claim 19 objected to because of the following informalities:

In line 3, before "band", there appears to be missing terminology. Appropriate correction is suggested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 13, 17, 26, 30, 31, 44, 48 and 49 are rejected under 35 U.S.C. § 102(b) as being anticipated by Soucy (US 3,387,624).

Regarding claim 1, Soucy teaches a fluid flow control valve comprising:
a double-duckbill valve (1) adapted to fluidly communicate with a fluid discharge passageway and having an inlet orifice (10) operable to control liquid flow therethrough;
said inlet orifice comprising at least a single slit (10)(see figure 10, below).

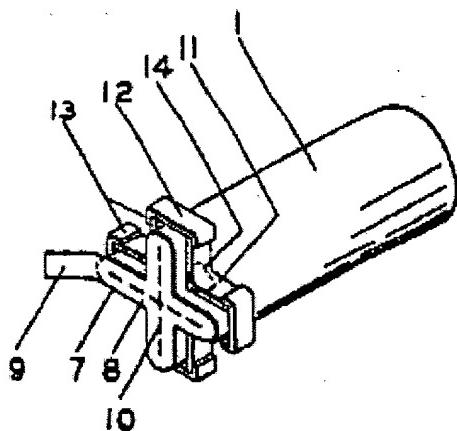


FIG. 10

Regarding the limitation which has the valve designed for use with a urine discharge passageway, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). There is no limitation in the claim which distinguishes the device from a generic liquid handling valve.

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Regarding claim 4, Soucy teaches an elastomeric band (11, 12) disposed about said double-duckbill valve (1) and operable to urge said inlet orifice to a closed position.

Regarding claim 13, Soucy teaches a crush limiting member (11) associated with said double-duckbill valve (1).

Regarding claim 17, Soucy teach a valve member (1) having a normally closed inlet orifice (10);

a separate elastomeric band (11, 12) disposed about said valve member (1) and operable to urge said inlet orifice to a closed position.

Regarding claim 26, Soucy teaches a crush limiting member (11) associated with said double-duckbill valve (1).

Regarding claim 30, Soucy teaches an inlet orifice (10) defined by at least a single slit.

Regarding claim 31, Soucy teaches a double-duckbill valve (figure 10).

Regarding claim 44, Soucy teaches a flow control valve comprising:
a valve member (1) having a normally closed inlet orifice (10);
a crush limiting member (11) associated with the valve member (1).

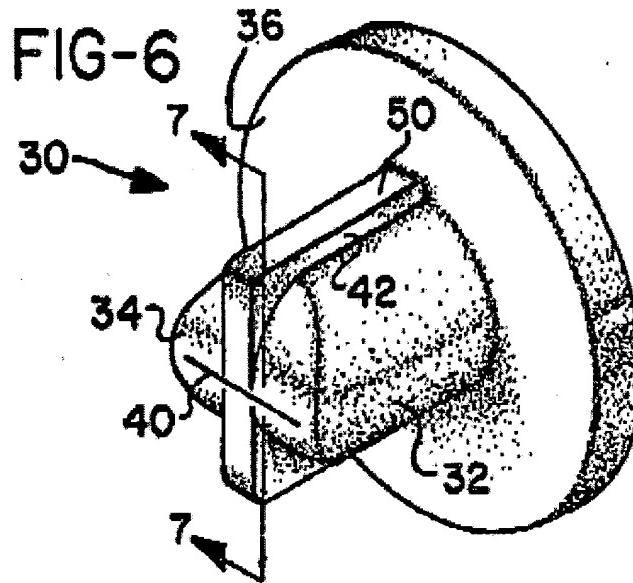
Regarding claim 48, Soucy teaches an inlet orifice (10) defined by at least a single slit.

Regarding claim 49, Soucy teaches a crush limiting member (11) associated with said double-duckbill valve (1).

Claims 1 and 2 are rejected under 35 U.S.C. § 102(b) as being anticipated by Atkinson (US 4,434,810).

Regarding claim 1, Atkinson teaches a fluid flow control valve comprising:

a double-duckbill valve (30) adapted to fluidly communicate with a fluid discharge passageway and having an inlet orifice (34) operable to control liquid flow therethrough; said inlet orifice comprising a single slit (40)(see figure 6, below).



Regarding the limitation which has the valve designed for use with a urine discharge passageway, there is no limitation in the claim which distinguishes the device from a generic liquid handling valve. See previous rejection of claim 1 by Soucy.

Regarding claim 2, Atkinson teaches a first duckbill structure (32) terminating at a first apex; and

a second duckbill structure (42) oriented perpendicular to said first duckbill structure and terminating at a second apex;

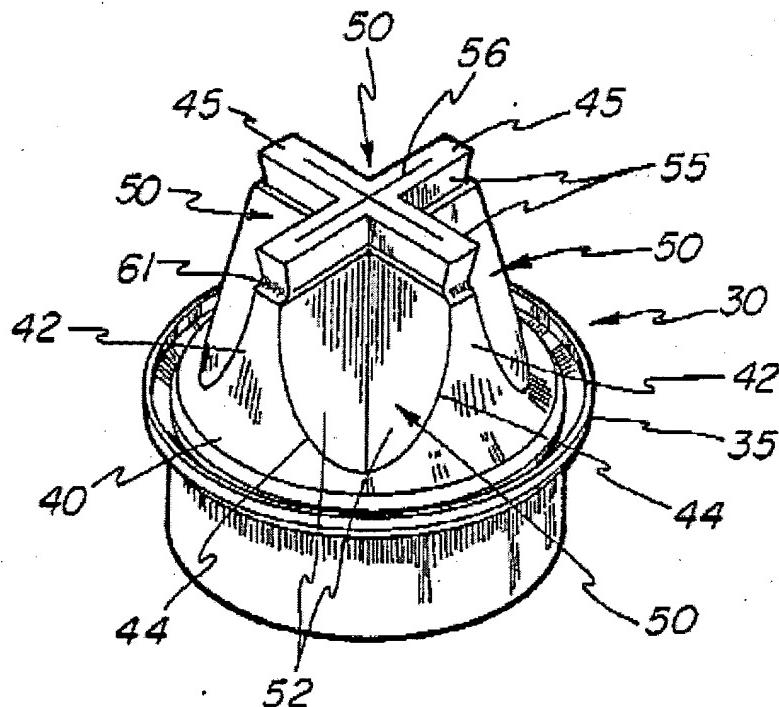
said first and second apexes defining said inlet orifice;

said slit (40) being formed in only one of said first and second apexes (34).

Claims 1, 5, 12, 38, 42 and 43 are rejected under 35 U.S.C. § 102(b) as being anticipated by Boehmer *et al.* (US 4,924,923).

Regarding claim 1, Boehmer *et al.* teach a fluid flow control valve comprising:
a double-duckbill valve (50) adapted to fluidly communicate with a fluid discharge
passageway and having an inlet orifice (45) operable to control liquid flow therethrough;
said inlet orifice comprising a single slit (56)(see figure 4, below).

FIG - 4



Regarding the limitation which has the valve designed for use with a urine discharge
passageway, there is no limitation in the claim which distinguishes the device from a generic
liquid handling valve. See previous rejection of claim 1 by Soucy.

Regarding claim 5, Boehmer *et al.* teach a valve housing (10) defined by at least one
wall; and

an isolating member (21) extending from said wall to said double-duckbill valve (50),
said double-duckbill valve (50) being supported in said valve

housing (10) in spaced relationship with said wall by said isolating member (21)(see figure 2, below).

Regarding claim 12, Boehmer *et al.* teach a valve housing (10) containing said double-duckbill valve (50);

said valve housing (10) having a discharge outlet (at junction of housing (10) and tank (11)) operatively coupled with said double-duckbill valve (50).

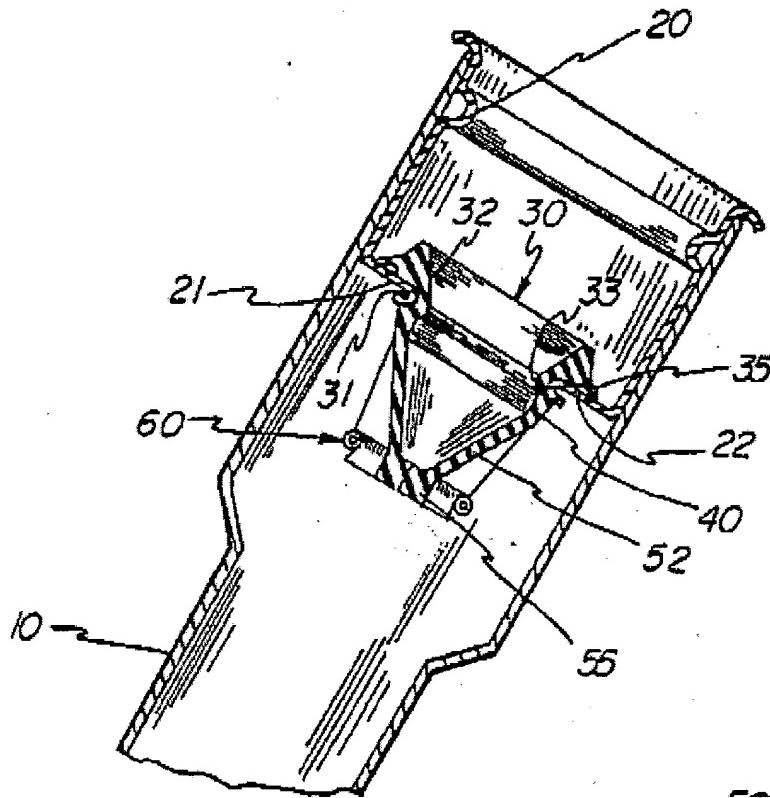
Regarding claim 32, Boehmer *et al.* teach a valve member (5) having a normally closed inlet orifice (56);

a valve housing containing (10) said valve member (50);
an isolation member (21) extending between said valve housing (10) and said valve member (50) whereby to support said valve member (50) in spaced relationship to said valve housing (10)(see figure 2, below).

Regarding claim 38, Boehmer *et al.* teach a crush limiting member in the form a a thickened cylindrical base (30) of the valve (50)(figure 4).

Regarding claim 42, Boehmer *et al.* teach an inlet orifice (45) defined by at least a single slit (56)(figure 4).

Regarding claim 43, Boehmer *et al.* teach a double-duckbill valve (50)(figure 4).

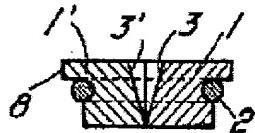


Claims 17-20 are rejected under 35 U.S.C. § 102(b) as being anticipated by Djordjevitch (3,066,767).

Regarding claim 17, Djordjevitch teaches a valve member (1, 1') having a normally closed inlet orifice (4);

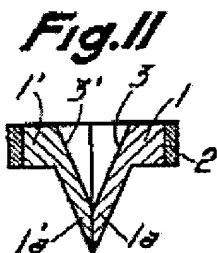
a separate elastomeric band (2) disposed about said valve member (1, 1') and operable to urge said inlet orifice (4) to a closed position (see figure 13, below).

Fig. 15



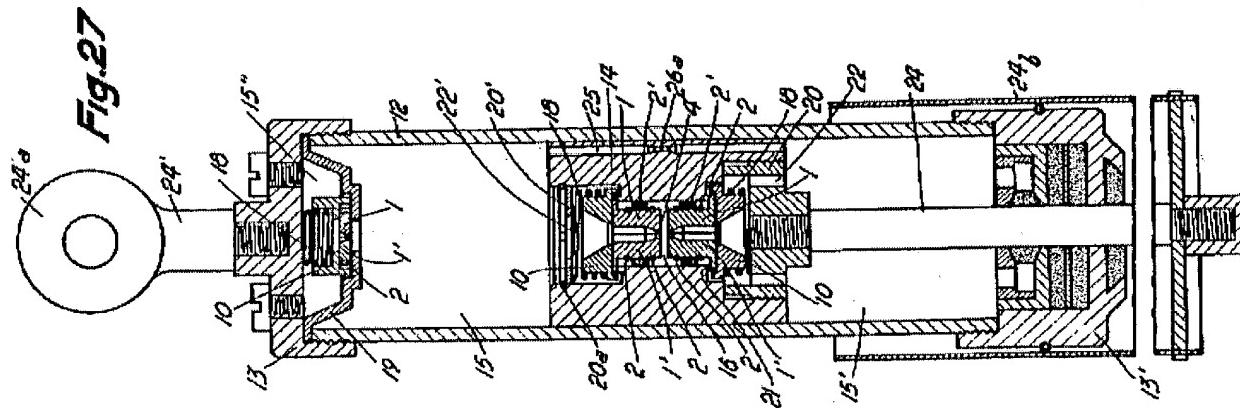
Regarding claim 18, Djordjevitch teaches a valve member (1, 1') which has a groove associate therewith, the elastomeric band (2) being situated in said groove (see figure 13, which shows band in a groove at the outside of the valve).

Regarding claim 19, Djorjevitch teaches a valve (1, 1') having a base and at least a pair of lips (1a, 1a') extending from said base at respective junctures of said lips (1a, 1a') with said base, the band (2) being positioned inwardly of said junctures of said lips with said base (see figure 11, below).



Regarding claim 20, Djordjevitch teaches a valve housing (12) containing said valve member (1, 1');

an isolation member (14) extending between said valve housing (12) and said valve member (1, 1') whereby to support said valve member (1, 1') in spaced relationship to said valve housing (12)(see figure 27, below).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

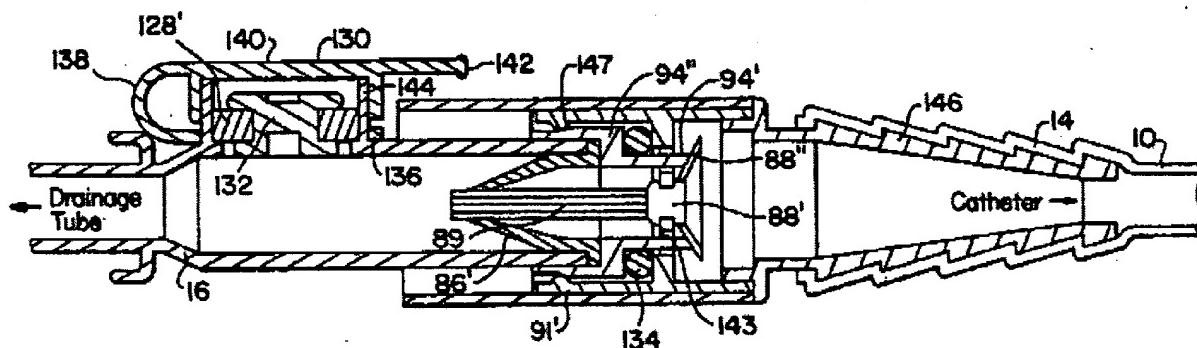
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 50, 53 and 55 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Davis (US 5,429,620 A) in view of Baumbach (US 3,565,106).

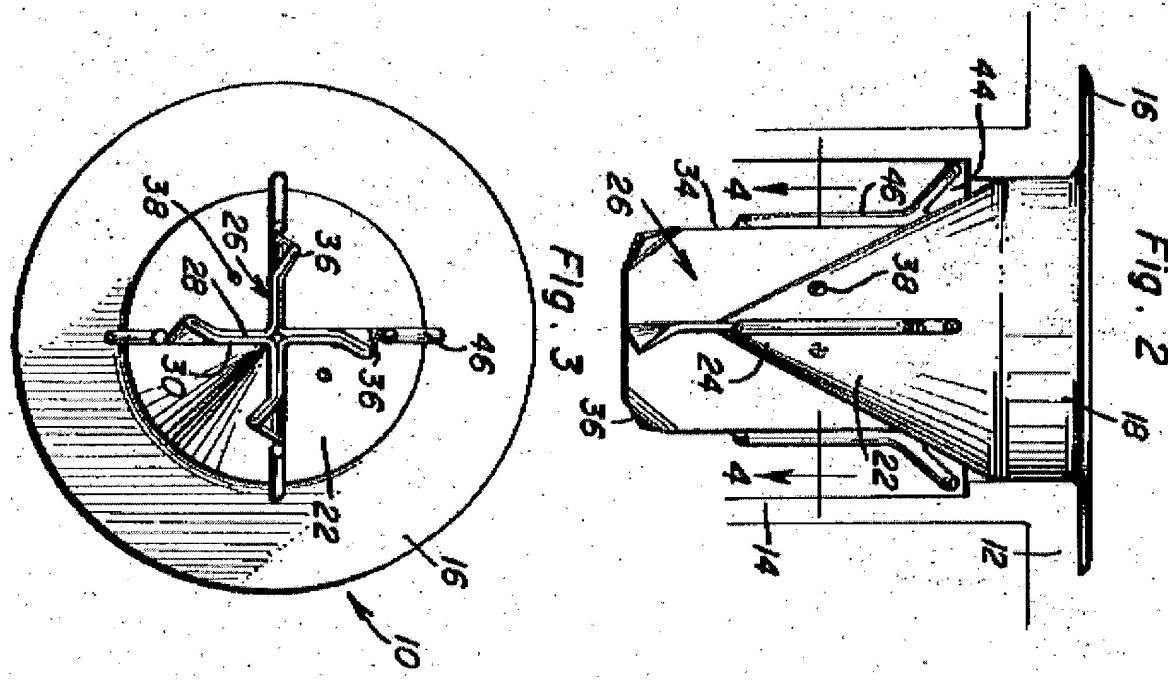
Regarding claim 50, Davis teaches a urinary catheter comprising;
a urine discharge passageway (10, 16);
a urine flow control valve (86) associated with said liquid discharge passageway (10, 16);
said urine flow control valve (86) being a duckbill valve;
said duckbill valve having an inlet orifice operable to control urine flow therethrough
(see figure 9, below).

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Davis expressly teaches the claimed invention except for the valve being a double-duckbill valve.

Baumbach teaches a spiraled double-duckbill valve (10) which is effective as a check valve in a variety of applications (see figures 2 and 3, below). This type of valve is especially resistant to being inverted by reverse liquid flow (Baumbach, column 2, lines 35-53).



At the time of the invention, it would have been obvious for one of ordinary skill in the art to substitute the spiraled double-duckbill valve of Baumbach for the conventional duckbill

valve in the catheter as taught by Davis in order to provide a valve with increased resistance to inversion cause by backflow.

Regarding claim 51, Baumbach teaches an inlet orifice defined by at least a single slit.

Regarding claim 55, Davis teaches a crush limiting member (94").

Allowable Subject Matter

Claims 3, 6-11, 15, 21-25, 28, 33-37, 40, 46 and 52-54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the examiner's supervisor, Larry Schwartz may be reached at phone number (571) 272-4390. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Bogart
19 November 2004


Larry I. Schwartz
Supervisory Patent Examiner
Group 3700